

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | | |
|---------------------------------------|---|------------------------|
| CAROL LEWIS, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Civil Action No.: |
| |) | 1:15-CV-13530-NMG |
| |) | |
| SYLVIA MATHEWS BURWELL |) | Leave to File Granted, |
| |) | March 4, 2016 |
| Secretary of the Department of Health |) | |
| and Human Services, |) | |
| |) | |
| Defendant. |) | |
| |) | |

DEFENDANT’S REPLY BRIEF

Plaintiff’s Response to Defendant’s Motion to Dismiss fails to establish that the Complaint meets the requirements of Rule 12(b)(1) and (6), Federal Rules of Civil Procedure, for the reasons set forth below:

I. PLAINTIFF’S CHALLENGE TO THE LCD IS NOT RIPE FOR REVIEW.

In Counts IV, V, and VI, Plaintiff seeks judicial review of the Defendant’s Local Coverage Determination that prohibits Medicare reimbursement for the costs of the continuous glucose monitors (“CGMs”) that she uses. Reimbursement is unavailable because HHS has determined that Plaintiff’s CGMs are “precautionary” medical devices and not medical devices “reasonable and necessary for the diagnosis of treatment of illness or injury.” 42 U.S.C.

§ 1395y(a)(1)(A).¹ See Defendant’s Memorandum of Law in Support of Motion to Dismiss

¹ Approved for Medicare reimbursement are other blood glucose monitors that Defendant considers reliable for purposes of making medical decisions, “meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient’s blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to

(“Dismiss Mem.”) at 4. However, Plaintiff’s challenge to the LCD is unripe for review because she has not exhausted the administrative remedies available to her, and, accordingly, the Court lacks jurisdiction to hear her LCD claims.

A Medicare beneficiary is entitled by statute to challenge the validity of an LCD pursuant to 42 U.S.C. § 1395ff(f) and 42 U.S.C. § 405(g) if she is an aggrieved party, that is, if she is “entitled to Medicare benefits under part A . . . or enrolled under Part B . . . or both, who are in need of the items or services that are the subject of the coverage determination.” 42 U.S.C. § 1395ff(f)(5); 42 C.F.R. § 426.400(c)(5). If the LCD is found invalid, the aggrieved party’s claim and all future claims by any Medicare beneficiary are evaluated by the Secretary without reference to the invalidated portions of the LCD. 42 U.S.C. § 1395ff(f)(2); 42 C.F.R. §§ 426.488, 426.460(b), 426.490.²

Plaintiff is not entitled to judicial review of her challenge to the LCD because she has not exhausted the administrative remedies related to that challenge. *See* Compl. ¶ 95, 97. As noted in Defendant’s Dismiss Mem. at 8-9, and as is undisputed, Plaintiff’s challenge to the LCD is proceeding before an agency Administrative Law Judge, where the parties are in the process of preparing for formal hearing. Dismiss Mem at 9. Final agency action for Plaintiff’s challenge will have occurred upon an appellate decision by the Department Appeals Board, after appeal from an adverse ALJ’s decision; *see* 42 C.F.R. § 426.490; *see* Dismiss Mem. at 6; which has not occurred because Plaintiff’s challenge regarding the LCD is only pending at the ALJ level of appeal. Accordingly, because Counts IV, V, and VI of the Complaint are limited to challenges

obtain a reading.” National Coverage Determination Manual, CMS Pub. No. 100-3, § 40.2. *See* 42 U.S.C. § 1395x(n).

² The challenge to an LCD is separate and independent of any challenge to denial of a beneficiary’s individual claims for Medicare coverage. *See* 68 Fed. Reg. 63393-94 (Nov. 7, 2003).

to the validity of the LCD, they should be dismissed because there has been no final agency action and the challenges are not ripe for review. *See Ernst & Young v. Depositors Economic Protection Corp.*, 45 F.3d 530, 534 (1st Cir. 1995) (subject matter jurisdiction lacking under Rule 12(b)(1) where challenge has not been exhausted through administrative procedures). *See also, Heckler v. Ringer*, 466 U.S. 602, 604-605 (19854).

II. THE COURT LACKS JURISDICTION UNDER THE APA TO REVIEW COUNTS I THROUGH VII OF THE COMPLAINT.

Plaintiff also filed a challenge before HHS on its denial to her individual claim for reimbursement for CGMs. That claim has been administratively exhausted – with a final, adverse decision -- and is ripe for judicial review. However, Plaintiff seeks judicial review of the decision under the Administrative Procedure Act and vigorously asserts the APA is the jurisdictional basis for review. Plaintiff has set forth no authority for her assertion and, as noted in Dismiss Mem. at 11-13, authority, including Supreme Court authority, is to the contrary. Accordingly, Counts I through VII should be dismissed.³

III. PLAINTIFF HAS NOT DEMONSTRATED A RIGHT TO MANDAMUS RELIEF.

Plaintiff has not demonstrated entitlement to an order requiring the Secretary to timely issue final administrative decisions on her individual claim or on her challenge to the LCD. *See* Dismiss Mem. at 13-15. *See generally, Cervoni v. Sec’y of Health, Ed., Welfare*, 581 F.2d 1010, 1019 (1st Cir. 1978) (noting that in order for mandamus to properly issue, plaintiff must demonstrate a clear right to the relief sought).

³ Plaintiff makes the equally puzzling assertion that Defendant has failed to provide her with a copy of the Administrative Record on her individual claim. Plaintiff’s Response at 5, 9. Defendant produced the Administrative Record to Plaintiff by first class mail on February 10, 2016, prior to filing of Plaintiff’s Response, as confirmed by email and telephone communications thereafter, also prior to filing of Plaintiff’s Response.

Plaintiff's mandamus request on her individual claim, is moot; both the administrative law judge ("ALJ") and the Medicare Appeals Council have issued decisions in her case, rendering the agency decision final. *See Randall Wolcott v. Sebelius*, 635 F.3d 757, 774 (5th Cir. 2011) (Plaintiff's claim for mandamus to compel removal of plaintiff from prepayment review for Medicare claims was moot because agency had already done so); *see also Ahmadabadi v. Lambrecht*, 2015 WL 7110796, at *3 (D. Colo. 2015) ("[a] petition for mandamus to compel an agency to act is rendered moot when the agency has taken action granting the relief requested in the mandamus petition.").

Plaintiff's mandamus request on her challenge to the LCD is also unsupportable. Her challenge to the LCD is on administrative appeal before an ALJ, in compliance with agency regulations. *See* Dismiss Mem. at 8-9. *See also*, 42 C.F.R. § 426.447, which provides:

An ALJ must issue to all parties to the LCD review, within 90 days of closing the LCD review record to the taking of evidence, one of the following:

- (a) A written decision, including a description of appeal rights.
- (b) A written notification stating that a decision is pending, and an approximate date of issuance for the decision.

Before the ALJ is permitted to close the LCD review record, the ALJ is required to: request the LCD record from HHS' contractor (42 C.F.R § 426.418), review responses to the LCD record from both Plaintiff and HHS' contractor (42 C.F.R. § 426.425(a)-(b)), and determine if the record is complete or if additional discovery and/or a hearing is needed (42 C.F.R. § 426.425(c)). If additional discovery is needed, the ALJ is required to establish a reasonable time frame for its submission. 42 C.F.R. § 426.432(a). In Plaintiff's challenge to the LCD, the ALJ determined that the initial record was incomplete and additional discovery was necessary; as a result, the ALJ ordered a discovery period, to be concluded by December 1, 2015. Plaintiff did

not contest the reasonableness of this order. The ALJ then conducted a pre-hearing conference and ordered both parties to further develop the record. Plaintiff's pre-hearing exchange was due to the ALJ on February 16, 2016. *See attachment*, ALJ's Scheduling Order of December 4, 2015. The ALJ has not yet closed the LCD review record. Because the record remains open, the 90-day time limit for issuing a written opinion or setting an approximate date for issuing a written opinion, has not yet started to run, and the ALJ is within the regulatory prescribed time frame for issuing a decision. Once the ALJ opinion is issued, an adverse opinion may be appealed to the Medicare Appeals Council, followed by review in the district court. Dismiss Mem. at 6-7.

Plaintiff request for mandamus relief relies on *American Hospital Ass'n, et al. v. Burwell* No. 15-5015, 2016 WL 491658 (D.C. Cir.). In that action, several hospitals requested that the Court order the HHS Secretary to comply with statutory deadlines when issuing administrative decisions on their claims for Medicare reimbursement. *Id.* at *1. The hospitals had not received hearings with an administrative law judge ("ALJ") and argued that the statutory escalation provisions to the Medicare Appeals Council ("MAC") or to U.S. District Court was an inadequate alternative remedy because escalation to a higher level of appeal did not guarantee them a right to an ALJ hearing. *Id.* at 7. The D.C. Circuit remanded to the District Court to determine whether mandamus was appropriate, holding that the escalation statute does not per se deprive the district court of jurisdiction to issue mandamus and suggesting that there could be compelling equitable grounds for issuance of mandamus orders to conduct ALJ hearings on appeals and for monitoring administrative appeals timeline performance in the context of agency appropriations, other statutory duties, etc. *Id.* at 16-19. *American Hospital* is irrelevant to

Plaintiff's request for mandamus in this action because the agency timeline is consistent with its legal requirements and the ALJ decision was not and is not overdue.

Respectfully submitted,

CARMEN M. ORTIZ
United States Attorney

/s/ Anita Johnson
ANITA JOHNSON BBO No. 565540
Assistant U.S. Attorney
One Courthouse Way, Suite 9200
Boston, MA 02210
617-748-3266
anita.johnson@usdoj.gov

Of Counsel:

WILLIAM B. SCHULTZ
Acting General Counsel

NANCY S. NEMON
Chief Counsel, Region I

JENNIFER WILLIAMS
Assistant Regional Counsel
Department of Health and Human Services
J.F.K. Bldg., Rm. 2250
Boston, MA 02203
617-565-2379
jennifer.williams@hhs.gov

Certificate of Service

I hereby certify that the foregoing will be filed through the electronic filing system of the Court, which system will serve counsel for Plaintiff electronically, on this fifteenth day of March 2016.

/s/ Anita Johnson